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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,020	06/28/2005	Kenji Fujii	Q88147	4034

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EXAMINER	
VAKILI, ZOHREH	
ART UNIT	**PAPER NUMBER**
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/541,020	FUJII, KENJI	
	Examiner	Art Unit	
	Zohreh Vakili	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-27 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-27 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :06/28/05, 11/14/06, 01/29/07, 4/18/07, 6/21/06, 01/29/07.

6/21/06.

DETAILED ACTION

Claims 1-27 are presented for examination.

LACK OF WRITTEN DESCRIPTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH:

Claims 5 and 8 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification discloses chemicals, such as compounds comprising of vitamin B, which meet the written description and enablement provisions of 35 USC 112, first paragraph.

However, claims 5 and 8 are directed to encompass derivatives, which only correspond in some undefined way to specifically instantly disclosed chemicals. None of these derivatives, meet the written description provision of 35 USC § 112, first paragraph, due to lacking chemical structural information for what they are and chemical structures are highly variant and encompass a myriad of possibilities. The specification provides insufficient written description to support the genus encompassed by the claim.

Vas-Cath, Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the

'written description' inquiry, *whatever is now claimed.* (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116).

With the exception of the above specifically disclosed chemical structures, the skilled artisan cannot envision the detailed chemical structure of the encompassed derivatives, analogs, etc., regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The chemical structure itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence. Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

> ...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.,* 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli,* 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the

written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

Therefore, only the above chemically structurally defined chemicals, but not the full breadth of the claim(s) meet the written description provision of 35 USC § 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC § 112 is severable from its enablement provision. (See page 1115).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as anticipated by WO 9807417.

WO 9807417 discloses a medicinal composition that comprises more than 20% by weight of a reduced coenzyme Q10 as an active component, and further indicates

that coenzyme Q10 may be necessary in order to alleviate physical fatigue; that coenzyme Q10 preparations can be configured with a dissolved form, an emulsified form or a dispersed form; and that the bioavailability of a reduced coenzyme Q10 is superior to that of an oxidized coenzyme Q10 (see abstract). WO 9807417 further discloses formula 1 and 2 (see page 1 and 4).

Thus, WO 9807417 disclose all limitations of and anticipate claims 1-3.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/07417, in view of JP 10-287560 A, taken with JP 10-53520 A, further in view of JP 7-330584, with JP 7-330593, and JP 2002-363073.

WO 9807417 discloses a medicinal composition that comprises more than 20% by weight of a reduced coenzyme Q10 as an active component, and further indicates that coenzyme Q10 may be necessary in order to alleviate physical fatigue; that coenzyme Q10 preparations can be configured with a dissolved form, an emulsified form or a dispersed form; and that the bioavailability of a reduced coenzyme Q10 is superior to that of an oxidized coenzyme Q10 (see abstract). WO 9807417 further discloses formula 1 and 2 (see page 1 and 4).

JP 10-287560 A teach of a pharmaceutical composition for replenishing nutrients for physical fatigue. The composition contains ubiquinone (corresponding to oxidized coenzyme Q10) and vitamin B1 (see abstract).

JP 7-330584 A teach of a fatigue ameliorant which contains ubiquinone and carnitine as active ingredients (see abstract).

JP 7-330593 A teaches of a medicine containing ubiquinone and biotin as active ingredients useful for treating diseases caused by physical and mental fatigue (see abstract)

JP 2002-363073 A teaches of a sport performance-improving agent that contains ubiquinone as an active ingredient. The agent is effective for preventing the occurrence

of physical and mental fatigues in sports, and stimulating recovery from fatigue occurred (see abstract).

All of the above mentioned references disclose agents for reducing fatigue, which comprise an ubiquinone (corresponding to oxidized coenzyme Q10) as the active component. On the other hand, JP 10-53520 A discloses anti-fatigue agents comprising a compound represented by formula (I), which has a chemical structure similar to that of an ubiquinone, as an active component; therein, JP 10-53520 A also indicates that it is possible to configure similar anti-fatigue agents from not only quinone-type (oxidized) species of ubiquinone, but also from hydroquinone-type (reduced) species of ubiquinone. Consequently, it would have been obvious to one of ordinary skilled in the art to attempt to determine what activity would result if a hydroquinone- type ubiquinone (i.e. a reduced coenzyme Q10) were used as the anti-fatigue agent in the inventions that are disclosed in the above mentioned references.

One would have been motivated to create such compounds because WO 9807417 indicates that reduced coenzyme Q10s are useful for promoting recovery from fatigue. Meanwhile, The other mentioned references disclose agents for reducing fatigue, wherein the active component is combined with other components which are useful for promoting recovery from fatigue, such vitamins, amino acids and anti-oxidizing agents. Therefore, one of ordinary skill in the art would have been motivated to attempt to add components which are known to be useful for promoting recovery from fatigue to the invention that is disclosed in WO 9807417, as appropriate.

One skilled in the art would have been motivated to combine the teachings of the above references considering that it is generally prima facie obvious to combine two or more compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a composition which is to be used for the very same purpose. The idea for combining them flows logically from their having been used individually in the prior art. As shown by the recited teachings, the instant claims define nothing more than the concomitant use of a fatigue reducing agent. It would follow that the recited claims define prima facie obvious subject matter. In re Kerhoven, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980).

Finally, one would have a reasonable expectation of success given that the above mentioned references have provided a detailed blueprint for making and using a fatigue reducing agent, and the steps of which are routine to one of ordinary skill in the art.

Thus in the absence of evidence to the contrary, the invention of claims 1-27 would have been prima facie obvious as a whole to one of ordinary skill in the art at the time the invention was made.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zohreh Vakili whose telephone number is 571-272-3099. The examiner can normally be reached on 8:30-5:00 Mon.-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Zohreh Vakili

Patent Examiner
1614

October 25, 2007

10/29/07
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER